DETAILED ACTION

Claims 46-51 are pending in this application for Patent; claims 40-45 being cancelled and claims 46-51 being newly added in the most recent amendment submitted by Applicant on 1/19/2010.

Claims 46-51 were examined on their merits.

10/610,909 and 10/439,301 are abandoned; subsequently, the previous double patenting rejections set forth over the claims of these applications are thus rendered moot and said rejections are removed herein.

The rejection of claims 41, 43, 44 and 45 under 35 USC 112 Second paragraph is herein removed due to Applicant's cancellation of these claims. Applicant did not introduce the indefinite phrase 'brain inflammatory processes' or the subject matter concerning beta-interferon to any of new claims 46-51 thus rendering said rejection moot.

The previous rejection of claims 40-45 under 35 USC 102(b) over Theoharides (WO 02/060393 A2) has been removed due to Applicant's inclusion of rutin into new claim 46.

The previous rejection under 35 USC 103(a) has been modified due to Applicant's amendments to the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

It is noted that Applicant has many patents and applications pending. Applicant is asked to make the Examiner aware of any potential double patenting issues in any other cases.

Claims 46-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,984,667 to Theoharides in view of Houston et al. (US 6,413,512) and Greenspan (US 6,551,575 B1). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-27 of '667 teach a composition with synergistic anti-inflammatory properties comprising non-bovine proteoglycan, unrefined kernel olive oil a flavonoid and a histamine-1-receptor antagonist, wherein the flavone is quercetin or myricetin (e.g., claim 18) and wherein the proteoglycan is chondroitin sulfate. Although Theoharides does not specifically teach the use of myrcetin and rutin as now required by claim 1, rutin was a known anti-inflammatory agent (see Houston et al., col. 11, lines 36-65). Although Theoharides does not specifically teach that rutin and myrcetin could

be used together, the combination of these elements would have been obvious considering that teach is a known anti-inflammatory and hence would have provided for at least an additive effect on inflammation. Although Theoharides did not specifically teach the use of hydroxyzine as a histamine-1-receptor antagonist, hydroxyzine was a known histamine receptor antagonist (see Greenspan et al., col. 33, lines 15-18). Hence, the ordinary artisan, having the claims of '667 before him or her, coupled with the knowledge that rutin was a known anti-inflammatory flavonoid and that hydroxyzine was a known histamine receptor antagonist, that these particular species of flavonoid and histamine antagonist respectively could have been predictably used in the invention of '667 absent evidence to the contrary.

Hence, the instant claims are, in the opinion of the Examiner, an obvious variation of the claims of the issued '667 patent in view of the secondary references.

Claims 46-51 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-2 of US 7,115,278. '278 teaches a composition comprising chondroitin sulfate, olive kernel extract, rutin and quercetin. However, the specification of this patent teaches that myricetin is also a suitable flavone to use. Therefore, the substitution of myricetin for quercetin in this '278 patent is an obvious variation of the patented claims of '278.

Claims 46, 50 and 51 are rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 of US 6,624,148. This '148 patent claims a composition comprising chondroitin sulfate, rutin and olive kernel extract (*inter alia*). Although the claim does not teach the inclusion of myricetin, the specification teaches that myricetin is a suitable flavonoid for use in the composition. Hence, the addition of myricetin is considered an obvious variation of claim 1 of this '148 patent.

Claims 46, 50 and 51 are rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 of US 6,635,625. This '148 patent claims a composition comprising shark cartilage, chondroitin sulfate, quercetin, rutin. and olive kernel extract (inter alia). Although the claims do not mention the inclusion of myricetin, myricetin is disclosed in the specification as being a suitable flavonoid for use in the composition, thus, the substitution of myricetin for quercetin in the claim is deemed an obvious variation of claim 1 of '625.

Claims 46, 50 and 51 are rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 of US 6,641,806. This patent claims a composition comprising chondroitin sulfate, quercetin and olive kernel extract (*inter alia*). Although the claims do not mention the inclusion of rutin, rutin is disclosed in the specification as being a suitable flavonoid for use in the composition, thus, the inclusion of rutin in the claim 1 of '806 is deemed an obvious variation.

Claims 46, 50 and 51 are rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 of US 6,645,482. This patent claims a composition comprising chondroitin sulfate, quercetin and olive kernel extract (*inter alia*). Although the claims do not mention the inclusion of rutin, rutin is disclosed in the specification as being a suitable flavonoid for use in the composition, thus, the inclusion of rutin in the claim 1 of '806 is deemed an obvious variation.

Claims 46-51 are provisionally rejected on the ground of nonstatutory double patenting over claims 40-44 49-55 and 57-61 of 10/811,838. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

These claims of '838 describe a composition comprising chondroitin sulfate, quercetin or myricetin, hydroxyzine and OKE. Therefore, claims 40-44 49-55 and 57-61 make obvious the claimed invention. The claims of '838 do not specifically teach the use of rutin in the composition, however, claim 40 of '838 specifically claims a flavonoid compound, and [0026] of '838 discloses that rutin is a suitable flavonoid. Hence, the use of rutin as the flavonoid in claim 40 to substitute for quercetin of '838 is an obvious variation of the patented claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theoharides (WO 02/060393 A2) in view of Houston et al. (US 6,413,512).

Theoharides (WO 02/060393 A2) discloses multiple compositions for treating inflammatory disorders such as multiple sclerosis (see entire WO document including the claims and Table 1). For treating these inflammatory conditions, Theoharides explicitly discloses several medicaments, including a composition comprising 50 mg chondroitin sulfate, 400 mg quercetin and 50 mg hydroxyzine, optionally in combination with interferon beta (see Example 10, p. 13). Example 13 on page 15 teaches a composition for protecting against skin allergy comprising non-bovine chondroitin sulfate, myrcetin, alpha tocopherol, unrefined kernel olive oil (which is an olive kernel extract) and optionally azelastine or hydroxyzine.

Theoharides did not explicitly teach the use of rutin in their composition.

Although Theoharides did not explicitly teach the use of rutin in their composition, Theoharides did specifically teach the use of anti-inflammatory flavonoids such as quercetin and myrcetin. Again, the crux of Theoharides was treatment of inflammatory disorders such as multiple sclerosis. Although Theoharides did not teach every known specific anti-inflammatory flavonoid, Theoharides broadly claim 'flavonoid.' In view of the specification of Theoharides, one would have been apprised that any suitable anti-inflammatory flavonoid could have been used in the composition. Rutin was a known anti-inflammatory agent at the time the Invention was made (see Houston et al., (US 6,413,512) col. 11, lines 36-65). Thus, one of ordinary skill in the art seeking suitable alternatives or seeking flavonoids to add to the composition of Theoharides would have had a reasonable expectation that rutin would have been a successful choice of flavonoid since it 1) closely resembles quercetin in structure (rutin and quercetin have the same core structure- quercetin being the aglycone of rutin) and 2) it is an anti-inflammatory flavonoid.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

In the Instant case, all of the above-listed ingredients were known anti-inflammatory agents. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in treating any inflammatory condition including brain inflammation in multiple sclerosis patients.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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